

From: [Lori Dixon](#)  
To: [Bill Jacobs/DC/USEPA/US@EPA](#)  
Subject: RE: Bait Station Questions  
Date: 12/08/2010 12:13 PM

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Thank you for the information listed below. I have yet another question...  
When you refer to Tier 4, 3, 2, 1....do these tiers impact the testing needed.  
My client wants Tier 1 and 3.  
Do both tiers require child, dog and adult testing?  
Thanks for your help.  
Lori

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-----Original Message-----

From: Jacobs.Bill@epamail.epa.gov [mailto:Jacobs.Bill@epamail.epa.gov]  
Sent: Wednesday, October 27, 2010 1:34 PM  
To: Lori Dixon  
Subject: Re: Bait Station Questions

Your questions from your inquiry of October 20, 2010, are addressed in order below.

1 - No. Your client could elect to use child-resistant packaging for the additional bait blocks, however.

2- Yes. Existing registrations for commensal rodenticide baits that are not sold in or with bait stations must be modified via label amendments to conform to conditions stipulated for such products in the Rodenticide Mitigation Decision (RMD) of May 28, 2008, if the registrations are to remain active after June 4, 2011. Products not compliant with the RMD may not be released for shipment after that date. Once a ready-to-use bait station product is registered, its registration may be amended, as long as the product remains a ready-to-use bait station. For example, an entity might apply for and receive a registration for a ready-to-use bait station product without submitting any data from child, dog, or adult-utility trials. Such a product would be labeled in the manner used for Tier 4 products. The registrant might subsequently amend the registration to Tier 3, Tier 2, or Tier 1 status by supplying appropriate additional data and modifying labeling accordingly.

3- The second generation anticoagulants are not to be sold on the "consumer" market or in "consumer-size" packages (<1 lb) after June 4, 2011. Second-generation anticoagulants may be sold on structural commercial-use and structural agricultural-use markets if they are sold in (outer) package sizes > 16 lbs and > 8 lbs, respectively, and are labeled as the RMD stipulates for such products. First-generation anticoagulant baits may be sold on those markets in (outer) package sizes > 4 lbs.

4- Generally, rat- and mouse-sized stations must be tested and registered separately, even if the units are of the same design and construction material(s). Size affects strength of units, accessibility through rodent entrances, and other potential ways to compromise them. Results in adult use trials could be affected by unit size. For examples, mouse-sized units could be harder for adults to manipulate or might be more likely to break upon use and reuse. Rat-sized units might require more effort than some adults can exert to perform tasks related to opening, refilling, and closing them. That having been said, we might consider exceptions to this approach on case-by-case bases. That likely would not occur until after we had examined the design that was tested and the design to which "bridging" of test data was being proposed. I also should mention that if two stations are of essentially identical design and size but one is to be refillable and the other is to be single-use (nonrefillable), the refillable version would be the one on which testing should be done. The theory here is that the refillable version would be the one more likely to be compromised in child and dog tests and the one more likely to present problems in adult utility trials.

5- A previously untested station is needed for each child and dog. For the adult tests, we would consider re-use of stations tested with other adults. However, the test protocol would have to include a requirement and criteria for inspecting units between trials to determine that they had not been damaged and that any feature pertaining to ease-of-use had not been modified. Incidences of such developments would have to be captured in the report of the trials submitted to EPA. (If units were to sustain damage during adult utility trials, that would be a "yellow flag" or a red one, depending upon how often damage occurred.)

Trials should be performed with production models, if possible. Production models are what customers will be using. Prototypes that are "being 'built'" individually should be pilot-tested to identify designs that are likely to be able to qualify as tamper-resistant (and to serve as efficient rodent baiters). Prototypes often are not made of the same material(s) as production models and may be glued together in places where production models are molded. Tabs on prototypes may differ in flexibility and "memory" from those on production units. In my experience, prototypes and production models typically differ somewhat in dimensions, including the thickness of corresponding components.

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| To:      |
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| Bill Jacobs/DC/USEPA/US@EPA
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| Date:    |
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| Bait Station Questions
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Several questions regarding rodent stations have come up. If you have any insights, I would appreciate your input. Thanks.

- 1) If the station comes with 2 blocks of bait in the station and four blocks outside of the station, in the same box, do the four that are not in the station have to be in a CR package?
- 2) If the bait is being sold today and has a registration, does the station (which is new) need a second registration?
- 3) They are using first generation bait, she was wondering if second generation is being phased out?
- 4) Does the rat (bigger) and mice (slightly smaller) both need to be tested and do they need separate registrations?
- 5) The stations are being "built" and they are expensive. Can any be reused for the test or does each adult need a new station? I would have to believe each kid needs their own station since they typically abuse them. I was wondering if, since they are refillable, packages could be reused?

She is new to this and we are not doing that many bait stations that these issues have come up that often. Thanks for your help. If easier, please feel to call my cell.  
cell: 419-351-3625

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